

CLERKS OFFICE U.S. DIST. COURT  
AT HARRISONBURG, VA  
FILED

OCT 03 2013

JULIA C. DUDLEY, CLERK  
BY: *h. b. o. t. s. m.*  
DEPUTY CLERK

IN THE UNITED STATES DISTRICT COURT  
FOR THE WESTERN DISTRICT OF VIRGINIA

United States of America, )  
Plaintiff, ) Civil Action No. 5:13-cv-0086  
v. )  
All articles of food in various size and type )  
containers, including non-integral metal and )  
glass containers, including ingredients, )  
in-process, and finished goods made )  
from interstate ingredients, that are located )  
anywhere on the premises of Royal Cup, Inc., )  
1300 Hopeman Parkway, Waynesboro, Virginia, )  
to which are affixed labels bearing, among )  
other things, the name and address of the )  
manufacturer, packer, or distributor located )  
outside the Commonwealth of Virginia, or which )  
are otherwise determined to consist in whole or )  
in part of ingredients that have originated )  
outside of the Commonwealth of Virginia, )  
Defendants. )

## **CONSENT DECREE OF CONDEMNATION**

On September 11, 2013, the United States of America, by its attorneys Timothy J. Heaphy, United States Attorney for the Western District of Virginia, and Kartic Padmanabhan, Assistant United States Attorney for this District, filed a Verified Complaint for Forfeiture *In Rem* (“Complaint”) against the above-described Defendant Articles (“Articles”). The Complaint alleges that the Articles proceeded against are articles of food that are adulterated, within the meaning of the Federal Food, Drug, and Cosmetic Act (the “Act”), 21 U.S.C. § 342(a)(4), while held for sale after shipment of one or more of their ingredients in interstate commerce, in that they have been prepared, packed, and held under insanitary conditions whereby they may have become contaminated with

filth. The Complaint further alleges that the Articles are being held illegally within the jurisdiction of this Court and, therefore, they are liable for seizure and condemnation under the Act, 21 U.S.C. § 334.

Pursuant to a Warrant of Arrest issued by this Court, the United States Marshal for this District seized the Articles on September 16, 2013 at 1300 Hopeman Parkway, Waynesboro, Virginia ("the Waynesboro Facility"). On September 20, 2013, Royal Cup, Inc. ("Claimant"), through its attorney, intervened and filed a claim to the seized Articles. Claimant represents that it is no longer storing food (other than the Articles) at or otherwise operating out of the Waynesboro Facility.

WHEREAS Claimant having appeared and consented, without contest, to entry of this Decree under 21 U.S.C. § 334(d) condemning all of the Articles under seizure and forfeiting them to the United States, and the Court having been fully advised of the basis thereof, pursuant to the request of the parties hereto, it is now

ORDERED, ADJUDGED, AND DECREED THAT:

1. This Court has jurisdiction over this action and the parties pursuant to 28 U.S.C. § 1335 and 21 U.S.C. § 334. Venue is proper in this District pursuant to 21 U.S.C. § 334(a) and 28 U.S.C. §§ 1391(b) and 1395.

2. Claimant affirms that it is the sole owner of the seized Articles and that no other person has an interest in the Articles. Claimant further affirms that it will indemnify and hold the United States harmless should any party or parties hereafter file or seek to file a claim or to intervene in this action, or seek to defend or to obtain any part of the Articles subject to this Decree.

3. The seized Articles are foods that are adulterated within the meaning of the Act, 21 U.S.C. § 342(a)(4), while held for sale after shipment of one or more of their ingredients in interstate

commerce, as alleged in the Complaint, and are therefore condemned pursuant to 21 U.S.C. § 334(a) and forfeited to the United States.

4. Pursuant to 21 U.S.C. § 334(e), Claimant shall pay to the United States all court costs and fees, service fees, storage costs, and other proper expenses of this proceeding incurred to date, and such further expenses, costs, and fees that may be incurred and taxed pursuant to 21 U.S.C. § 334(e). Claimant shall pay these costs within ten (10) calendar days after receiving notice of such costs from the U.S. Food and Drug Administration ("FDA"), the United States Marshals Service, or the United States Attorney for this District.

5. Within twenty (20) calendar days of the date of entry of this Decree, Claimant shall execute and file with the Clerk of this Court a good and sufficient penal bond with surety ("Bond") in the amount of eighty thousand dollars (\$80,000.00), in a form acceptable to the Clerk of this Court and payable to the United States of America, and conditioned on Claimant's abiding by and performing all of the terms and conditions of this Decree and of such further orders and decrees as may be entered in this proceeding.

6. Claimant shall not commence, permit any other person to commence, or cause any other person to commence, attempting to move the Articles from the Waynesboro Facility or otherwise attempting to bring the Articles into compliance with the law unless and until the following conditions have been met:

A. Claimant, at its own expense, hires a person or persons (the "Expert") with no personal or financial ties (other than the consulting agreement) to Claimant and who, by reason of education, training, and experience, is qualified to develop and implement a reconditioning plan to

bring the Articles into compliance with the Act, and Claimant informs FDA in writing of the name and qualifications of the Expert as soon as it retains the Expert;

B. The Expert develops a written reconditioning plan (the "Proposal"), which shall include, but not be limited to:

(i) documentation regarding the pest control services at the location where Claimant proposes to move and store the Articles (the "New Location");

(ii) a description of the layout of the New Location, including a description of where Claimant intends to store the Articles;

(iii) a description of how the Articles are to be packed and transported to the New Location;

(iv) a certification from the Expert that the New Location is fit for the proper storage and handling of food and that the New Location has a quarantine area such that storage of the Articles to the New Location will not result in the adulteration of any additional food; and

(v) a description of how Claimant proposes to recondition the Articles to bring them into compliance with the Act.

C. The Expert submits the Proposal to FDA in writing at the address specified in Paragraph 23;

D. Claimant receives written notification from FDA approving the Proposal developed by the Expert;

E. Claimant pays the costs pursuant to Paragraph 4 and posts the Bond specified in Paragraph 5;

F. Claimant informs FDA in writing, at the address specified in Paragraph 23, that Claimant, at its own expense, is prepared to attempt to bring the Articles into compliance with the law under the supervision of a duly authorized representative of the FDA ("FDA representative") and in accordance with the approved Proposal described in Paragraph 6(D);

G. Claimant receives written notification from FDA that the premises where Claimant intends to store the Articles are clean and suitable for the storage of food; and

H. Claimant receives written authorization from FDA to commence attempting to bring the Articles into compliance with the law.

7. Claimant shall at no time, and under no circumstances whatsoever, receive, accept for storage, or store any additional articles of food at the Waynesboro Facility unless and until FDA has determined that the Waynesboro Facility has been rendered sanitary and fit for the proper storage and handling of articles of food.

8. Following Claimant's payment of costs and posting of the Bond as required by Paragraphs 4, 5, and 6(E) of this Decree, and following Claimant's receipt of written authorization to commence reconditioning as described in Paragraph 6(H), the United States Marshal for this District shall release the Articles from his custody to the custody of Claimant for the sole purpose of attempting to bring the Articles into compliance with the law pursuant to the approved Proposal described in Paragraph 6(D).

9. Claimant shall at all times, until the Articles have been released in writing by an FDA representative for shipment, sale, or other disposition, retain the Articles intact for examination or inspection by the FDA representative, in a place made known to and approved by the FDA

representative, and shall retain the records or other proof necessary to establish the identity of the Articles to the satisfaction of the FDA representative.

10. Claimant shall at no time, and under no circumstances whatsoever, ship, sell, offer for sale, or otherwise dispose of any part of the Articles until: (a) an FDA representative has had free access to the Articles in order to take any samples or make any tests or examinations that are deemed necessary; and (b) the FDA representative has, in writing, released the Articles for shipment, sale, or other disposition.

11. Within thirty (30) calendar days of receiving written authorization to commence attempting to bring the Articles into compliance with the law, Claimant shall complete its attempt in accordance with the Proposal approved pursuant to Paragraph 6(D), and under FDA's supervision. Claimant shall destroy, at its own expense and under FDA's supervision, any Article that has not been brought into compliance within the thirty (30) calendar-day period. The FDA representative's decision regarding the adequacy of Claimant's attempt to bring the Articles into compliance with the law shall be final.

12. Claimant shall not sell or dispose of the Articles or any part of them in a manner contrary to the provisions of the Act, or any other federal law, or of the laws of any state or Territory (as defined in the Act) in which they are sold or disposed of.

13. If requested by an FDA representative, Claimant shall furnish duplicate copies of invoices of sale of the Articles, or such other evidence of disposition as the FDA representative may request.

14. If Claimant breaches any conditions stated in this Decree, or in any subsequent decree or order in this proceeding, Claimant shall, at its own expense, immediately return any of the

Articles to the United States Marshal for this District or otherwise dispose of them pursuant to further order of this Court. In the event that return of any of the Articles becomes necessary pursuant to this Paragraph, Claimant shall be responsible for all costs of storage and disposition that are incurred by the United States.

15. If, within ninety (90) calendar days of the entry of this Decree, Claimant does not avail itself, in the manner stated in the Decree, of the opportunity to repossess the Articles, the United States Marshal for this District shall destroy such Articles and make due return to this Court regarding their disposition. Claimant shall bear the costs of storage and destruction that are incurred by the United States pursuant to this Paragraph, and shall pay such costs within twenty (20) calendar days of receiving an invoice from FDA, the United States Marshals Service, or the United States Attorney for this District.

16. Claimant shall abide by the decisions of FDA, which decisions shall be final. FDA decisions under this Decree shall be reviewed by the Court, if contested, under the arbitrary and capricious standard set forth in 5 U.S.C. § 706(2)(A). Review shall be based exclusively on the written record before FDA at the time the decision was made. No discovery shall be authorized or allowed by either party.

17. Claimant shall bear its own costs and attorneys' fees in connection with this action.

18. Should the United States bring, and prevail in, a civil or criminal contempt action arising out of the violation of any term of this Decree, Claimant shall, in addition to other remedies, reimburse the United States for its attorneys' fees, investigational expenses, expert witness fees, travel expenses incurred by attorneys and witnesses, and administrative court costs relating to such contempt proceedings.

19. Claimant shall reimburse the United States for the costs of supervision of Claimant's attempt to bring the Articles into compliance with the law, including all inspections, examinations, reviews, evaluations, and analyses conducted pursuant to this Decree, at the standard rates prevailing at the time the activities are accomplished. As of the date this decree is signed by the parties, the rates are: \$87.57 per hour and fraction thereof per representative for inspection or investigative work; \$104.96 per hour or fraction thereof per representative for analytical or review work; \$0.565 per mile for travel expenses by automobile; government rate or the equivalent for travel by air or other means; and the published government per diem rate or the equivalent for the areas in which the inspections are performed per day, per representative for subsistence expenses, where necessary. In the event that the standard rates applicable to FDA supervision of court-ordered compliance are modified, these rates shall be increased or decreased without further order of the Court.

20. If Claimant fails to abide by and perform all the terms and conditions of this Decree, or of the Bond, or of such further order or Decree as may be entered in this proceeding, then the Bond shall, on motion of the United States in this proceeding, be forfeited in its entirety to, and judgment entered in favor of, the United States.

21. The United States Attorney for this District, upon being advised by an FDA representative that the Articles have been brought into compliance with the Act and the requirements of this Decree, or destroyed in compliance with this Decree, and that Claimant has paid all costs submitted to Claimant as of that date, will transmit such information to the Clerk of this Court, whereupon the Bond given in this proceeding shall be returned to the Claimant.

22. Representatives of FDA shall be permitted, without prior notice and as and when FDA deems necessary, to make inspections of the Waynesboro Facility or the New Location, and,

without prior notice, take any other measures necessary to monitor and ensure continuing compliance with the terms of this Decree. During such inspections, FDA representatives shall be permitted access to buildings, equipment, articles of food, containers, and packaging material(s) therein; to take photographs and make video recordings; to take samples of articles of food, containers, and packaging material(s); to examine and copy all records relating to the receiving, processing, preparing, packing, holding, and distributing of any and all articles of food, and/or relating to the sanitation of the facility. The inspections shall be permitted upon presenting a copy of this Decree and appropriate credentials. The inspection authority granted by this Decree is separate from, and in addition to, the authority to make inspections under the Act, 21 U.S.C. § 374.

23. All notifications, correspondence, and communications to FDA required by this Decree: (a) shall be addressed to the Director, Baltimore District Office, U.S. Food and Drug Administration, Department of Health and Human Services, 6000 Metro Drive, Suite 101, Baltimore, Maryland 21215; (b) shall reference the civil action number; and (c) shall be prominently marked "Royal Cup, Inc. Consent Decree Correspondence."

24. This Court retains jurisdiction over this action for the purpose of enforcing or modifying this Decree and for the purpose of granting such additional relief as may be necessary or appropriate.

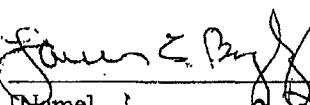
SO ORDERED:

Dated this 3rd day of October, 2013.

*1/s/ Michael F. Urbanski*

MICHAEL F. URBANSKI  
United States District Judge  
Western District of Virginia

We hereby consent to entry of the forgoing consent Decree:

<i>For Claimant Royal Cup, Inc.</i>	<i>For the United States of America</i>
 [Name] Lamer E. Bagby Royal Cup, Inc. Vice President - Financial  ERICA W. BARNES Maynard Cooper & Gale, PC 1901 Sixth Avenue North 2400 Regions Harbert Plaza Birmingham, AL 35203 (205) 254-1115  <i>Attorney for the Claimant</i>	 TIMOTHY J. HEAPHY UNITED STATES ATTORNEY   KARTIC PADMANABHAN Assistant United States Attorney Virginia State Bar No. 74167 P.O. Box 1709 Roanoke, VA 24008 (540) 857-2983  OF COUNSEL:  WILLIAM B. SCHULTZ General Counsel  ELIZABETH H. DICKINSON Chief Counsel Food and Drug Division  ANNAMARIE KEMPIC Deputy Chief Counsel, Litigation  SONIA W. NATH Associate Chief Counsel for Enforcement United States Department of Health and Human Services Office of the General Counsel 10903 New Hampshire Ave. Silver Spring, MD 20993-0002 (301) 796-8708  <i>Attorneys for the United States of America</i>